

UK Patent Application

GB 2 202 150 A

(43) Application published 21 Sep 1988

(21) Application No 8804898

(22) Date of filing 1 Mar 1988

(30) Priority data

(31) 8706116 (32) 14 Mar 1987 (33) GB

(51) INT CL:
A61F 13/02 A61M 25/02

(52) Domestic classification (Edition J):
A5R BA

(56) Documents cited
US 4275721

(58) Field of search
A5R
Selected US specifications from IPC sub-classes
A61F A61M

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(54) Adhesive dressings, their preparation and use

(57) A dressing for retaining a cannula on the skin comprises a backing film (1) coated on one face with an adhesive layer and with first (8) and second (11) release sheets covering the adhesive layer. A hole (4) and a dividing line (3) are cut through the dressing and second release sheet so that the dividing line extends from the hole to one edge of the dressing and the edge of the second release sheet. In use when the second release sheet is removed the hole in the dressing fits around the indwelling cannula. In a preferred form a portion of the dressing comprises an adhesive coated handle (2) which is stiffer than the remainder of the dressing and which carries the hole and dividing line.

The adhesive layer may carry an antibacterial agent such as chlorhexidine diacetate.

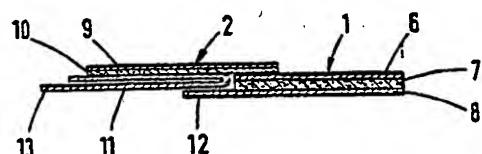
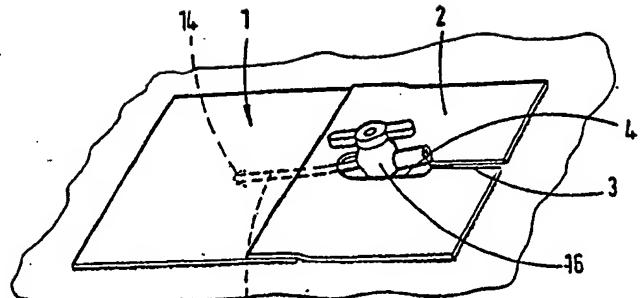
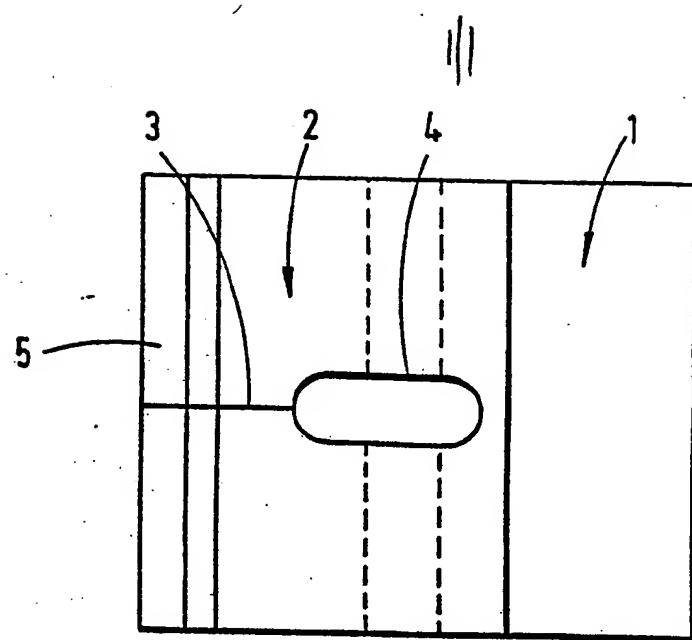


Fig. 2



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Fig. 1

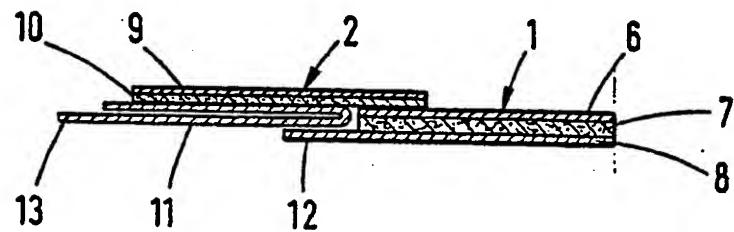
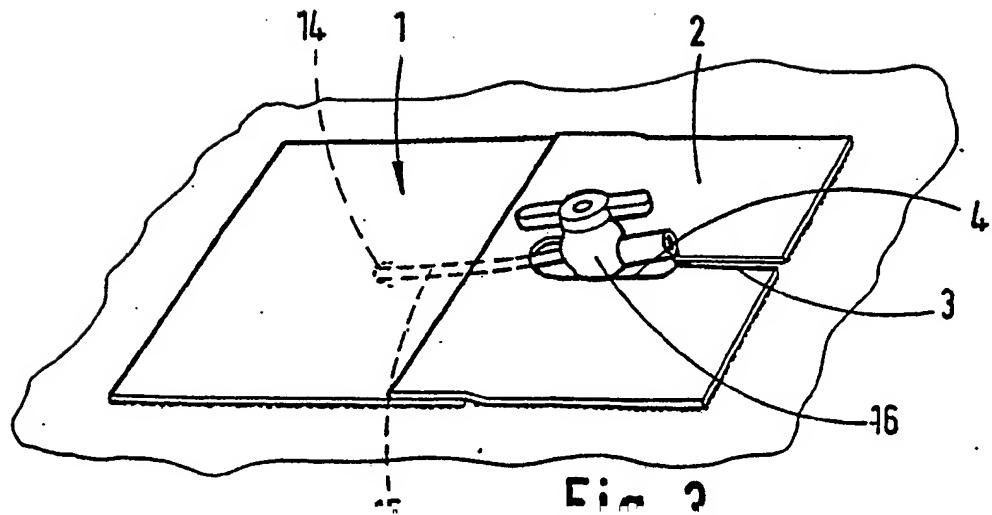


Fig. 2



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ADHESIVE DRESSINGS, THEIR
PREPARATION AND USE

5 The present invention relates to an adhesive dressing which is suitable for use on skin for the fixation of a catheter or a cannula and which comprises a backing film coated on one face with an adhesive layer and first and second release sheets covering the

10 adhesive layer and which dressing is adapted to adhere around a connection device at the proximal end of the cannula or catheter to prevent ingress of bacteria to the injection site; to methods of their preparation and use.

15 Adhesive dressings such as Opsite (Trade mark) are frequently used to cover and secure a catheter or cannula in place at an intravenous access site. Such dressings may be referred to as i.v. dressings.

5 Commercially available i.v. dressings typically
comprise a thin moisture vapour permeable sheet material
which has on one surface a skin compatible pressure
sensitive adhesive which is in turn covered by a single
sheet removable protector. In use the dressing is
10 adhered so as to cover the intravenous access site and
the catheter or cannula. One problem with such
dressings is that usually a bulky connector or hub is
present at the proximal end of the catheter or cannula
whereby connection can be made with a source of infusion
15 fluid. This is usually in the form of a female luer
lock component. Other devices may be present at this
hub such as taps or injection ports or the like. The
connector or hub being necessarily exposed to the
atmosphere can provide a pathway whereby bacteria may
20 reach the injection site since the connector cannot be
totally enclosed beneath the dressing. One way of over-
coming this problem is to use two types of dressing one
covering the injection site and the second ensuring that
bacteria cannot migrate from the connector along the
25 catheter or cannula to the injection site.

A dressing has now been developed which simplifies
the protection of injection sites for indwelling
catheters and cannulae by providing a dressing which
both covers the injection site and is adapted to retain

5 any connector associated with the catheter or cannula in place with reduced risk of bacteria migrating to the injection site.

A second problem which is sometimes observed with such dressings is that once the protector has been 10 removed the thin filmic adhesive dressing creases, puckers or otherwise sticks to itself and must be discarded. Many dressings have therefore included extra stiffening layers or frames or handles in an attempt to 15 overcome this problem. However, the dressings of this invention mitigate this problem by providing the protector as a first release sheet and a second release sheet so that the first release sheet is removed to expose the adhesive on the part of the dressing which is to cover the injection site and the second release sheet 20 is then removed to expose the remaining adhesive surface which is used to maintain the catheter or cannula in place. The second release sheet, which is folded, stabilises the dressing after removal of the first sheet and during application of the dressing.

25 Accordingly the present invention provides a dressing for retaining a cannula comprising a backing film coated on one face with an adhesive layer and first and second release sheets covering the adhesive layer

5 characterised in that there is a hole and a dividing line through the dressing and second release sheet said dividing line extending from the hole to one edge of the dressing and second release sheet whereby when the second release sheet is removed the hole in the dressing
10 is adapted to be placed around the cannula.

By dividing line is meant a means to enable the dressing on one side of the dividing line to be separated from the dressing on the other side. A dividing line may include for example cuts and lines of perforations. Preferably the dividing line is a line of
15 perforations.

The dividing line allows the hole and the part of the dressing around the dividing line to be placed easily around, and subsequently secure, a catheter or
20 cannula lying on the skin.

Suitable backing films include polymeric films, papers, woven and nonwoven fabrics, but preferably the backing film comprises a flexible polymeric film. The film may comprise any of the flexible polymeric films conventionally used in i.v. dressings. The flexible
25 film is aptly a moisture vapour permeable and bacteria proof film. In addition it is most convenient to employ

5 a transparent material. Favoured moisture vapour
permeable, liquid water impermeable, flexible films will
have a moisture vapour transmission rate of at least 300
gm⁻² 24h⁻¹ at 37°C at a relative humidity difference of
100% to 10%, more suitably at least 400 gm⁻² 24h⁻¹,
preferably at least 500 gm⁻² 24h⁻¹ and most preferably
at least 700 gm⁻² 24hr⁻¹.

10 Suitable flexible films for use in the invention
include those described in British Patent No. 1280631
and European Patent Application Nos. 51935, 178740 and
15 196459. Favoured flexible polymeric films include those
formed from a polyether or polyester polyurethane.
Suitable polyether and polyester polyurethanes include
those known as Estanes (Trade mark, available from B.F.
Goodrich Corp.). Preferred polyurethanes are available
20 as Estanes 5701, 5702, 5703, 5714 and 580201. A second
particularly favoured flexible film may be formed from
an elastomeric polyether polyester. Preferred polyether
polyesters include Hytrel 4056 (Trade mark, available
from E.I. du Pont de Nemours & Co.). A third
25 particularly favoured polymeric flexible film may be
formed from a polyether polyamide. Preferred polyether
polyamides include Pebax 4011 (Trade mark).

5 Suitably the thickness of the flexible films used
in the invention may be from 9 to 80 μ m, more suitably 15
to 50 μ m and preferably 20 to 40 μ m for example 25 μ m, 30 μ m
or 35 μ m.

10 A second favoured form of flexible film may be
formed from any moisture vapour permeable transparent
hydrophilic polymer. Suitable materials include
polyurethanes, polyether polyesters, polyether
polyamides, cellulosics and the like.

15 A favoured flexible film of hydrophilic polymer is
formed from a hydrophilic polyurethane. Suitable
hydrophilic polyurethanes include those having the
composition and prepared by the process described in
British Patent No. 2093190B. Favoured hydrophilic
polyurethanes are those which contain from 5 to 50% by
20 weight of water when hydrated, more suitably 10 to 40%
by weight of water and which have a thickness when
present in a dressing of from 15 to 80 μ m, more suitably
20 to 45 μ m. A preferred film of hydrophilic
polyurethane has a water content when hydrated of 20 to
25 30% for example 25% and a thickness of 20 to 45 μ m, for
example 30 μ m.

5 Suitably the adhesive layer on the dressing
may be 15 to 65 μm thick, preferably is 20 to 40 μm thick,
for example 25, 30 or 35 μm thick. Such adhesive layers
will generally have a weight of adhesive per unit area
of 10 to 75 gm^{-2} , more usually 15 to 65 gm^{-2} and
10 preferably 26 to 40 gm^{-2} .

Suitable adhesives include those which are
described in British Patent No. 1280631 and European
Patent Applications Nos. 51935, 35399. Preferably, the
adhesive is a polyvinyl ether adhesive such as polyvinyl
15 ethyl ether adhesive or an acrylate adhesive such as an
acrylate ester copolymer adhesive. Examples of the
latter include acrylate ester copolymers which contain
hydrophilic groups, for example a copolymer of 47 parts
by weight butyl acrylate, 47 parts by weight
20 2-ethylhexyl acrylate and 6 parts by weight acrylic
acid.

The adhesive may be applied to the backing film as
a continuous layer or as a discontinuous layer for
example as a pattern spread layer, a porous layer.

25 Since the dressings of the present invention are to
be adhered to normal healthy skin then to avoid
maceration of that skin it is arranged that the dressing
will have a moisture vapour permeability of at least 300

5 gm⁻² 24h⁻¹ at 37°C and 100% to 10% relative humidity,
more suitably will be at least 500 gm⁻² 24h⁻¹ and
preferably will be at least 700 gm⁻² 24h⁻¹.

10 Suitably the adhesive may contain a medicament such
as an antibacterial agent. Suitably the adhesive may
contain from 1 to 10% by weight of the adhesive as
medicament.

15 Suitable antibacterial agents include chlorhexidine
and salts thereof such as chlorhexidine diacetate and
chlorhexidine digluconate, iodophors such as polyvinyl
pyrrolidone-iodine, silver salts such as silver
sulphadiazine and polymeric biguanides for example those
antibacterial agents known as Vantocil (Trade mark)
which is polyhexamethylene biguanide hydrochloride.

20 In a preferred dressing the adhesive contains 5% by
weight of the adhesive of chlorhexidine diacetate.

25 In a preferred form of this dressing one portion of
the dressing is a handle. The handle will have an
adhesive layer on one surface so that it may be adhered
to the skin of the patient when the dressing is in
place. Normally prior to application of the dressing
this adhesive layer will be covered by the second

5 release sheet. In use the handle and its associated
release sheet may be held in the hand whilst the first
release sheet is removed from the remainder of the
dressing. The adhesive coated layer is then applied
over the skin puncture site. The second release sheet
10 may then be removed and the handle adhered to the skin.
The handle is made from a different material to the rest
of the dressing and since it is not meant to cover the
skin puncture site need not be bacterial-proof through
this property is desirable. It is clear therefore that
15 in a preferred form the backing layer of the dressing
comprises a handle and a flexible sheet which forms the
rest of the dressing. The flexible sheet is aptly
formed from any of the materials which are suitable for
the backing layer as described hereinbefore especially a
20 moisture vapour permeable, liquid water impermeable,
flexible polymeric film. The handle may be attached to
the rest of the dressing by any conventional means such
as adhesives or by bonding the handle and flexible sheet
together by means of heat. In this preferred form of
25 the dressing the hole and dividing line are located in
the handle of the dressing.

From the foregoing it is clear that the adhesive
surface on the handle and the adhesive surface on the

5 flexible sheet will be on the same side so that both may
be adhered to the body.

10 The handle used in the dressing of the invention
can suitably be a film, sheet or web. Suitable handles
can be made of a wide variety of materials including
paper, non-woven fabric, woven fabric and films, sheets
or webs of polymers including polypropylene,
polyethylene, copolymers thereof and blends thereof and
blends including polystyrene, polyester and polyvinyl
chloride.

15 Particularly apt materials for forming the handle
include paper, porous polyvinyl chloride sheet such as
that sometimes known as Porvic (Trade mark) which is
conventionally used in the manufacture of first aid
dressings, non-woven fabric such as spun-bonded
20 polyester fabric (Sontara, Trade mark), polyester film
(Melinex, Trade mark), woven acrylic fabric, embossed
films of low or high density polyethylene or
polypropylene, integral nets formed by the fibrillation
of embossed films and oriented polypropylene films.

25 However, particularly preferred materials for
forming the handle are integral nets particularly those
formed by the fibrillation of thermoplastic embossed

5 polyolefin films comprising low and high density polyethylene, polypropylene or copolymers or blends thereof or blends of polyolefin with polystyrene. Such nets are described in British Patents Nos. 1495151 and 1531715.

10 The handle has a dividing line extending inwardly from the edge of the handle in a direction towards the flexible sheet portion of the backing film of the dressing. The dividing line leads to the hole cut within the area of the handle. The hole preferably 15 extends into the overlap area where the handle and flexible sheet overlap.

20 The hole may be of any shape such as square, rectangular, circular, oval and the like. It is preferred that the hole is oval in shape as this shape accommodates the shape of the connector and thereby forms a better seal between the dressing and the connector. Suitably the long axis of the hole may be from 20 to 30mm in length and preferably 23 to 27mm in length for example 25mm and the short axis of the hole 25 may be from 5 to 15mm, and preferably 7 to 11mm for example 9mm.

5 The second release sheet which may cover the exposed adhesive of the handle when present may be in a folded form and may be cut along with the handle so that the release sheet has a slit and opening or alternatively the release sheet may be merely
10 perforated.

The handle may be colour coded, for example the handle may be green or yellow or pink.

15 Since the handle is to be adhered to the skin it is preferred that the handle when coated with adhesive should have a moisture vapour transmission rate of at least $300\text{gm}^{-2} 24\text{h}^{-1}$ at 37°C and 100% to 10% relative humidity when measured by the Payne Cup Method. More suitably the adhesive coated handles should have a rate of at least $500\text{gm}^{-2} 24\text{h}^{-1}$ and preferably should be at least $700\text{gm}^{-2} 24\text{h}^{-1}$. The handle may then be safely adhered to the skin without the risk of causing maceration to the underlying normal healthy skin.

25 An adhesive such as one of those described in British Patent No. 1280631 or European Patent Application No. 35399 may be spread onto the smooth surface of the net as hereinbefore described, that is the one which was embossed with the series of grooves.

5 A particularly suitable adhesive is an acrylate ester copolymer adhesive formed from the polymerisation of 47 parts 2-ethylhexyl acrylate, 47 parts butyl acrylate and 6 parts acrylic acid. This combination of net and adhesive gives a tape of both high moisture vapour
10 permeability which is particularly apt for the dressings of the present invention. If the adhesive layer is continuous the moisture vapour transmission rate is approximately $800\text{gm}^{-2} 24\text{h}^{-1}$ and if the adhesive layer is porous the rate may be as high as $8000\text{gm}^{-2} 24\text{h}^{-1}$, when measured at 37°C and 100% to 10% relative humidity.
15

20 Suitably the handle may be 1.0cm to 6.0cm in width and preferably 2.0 to 5.0cm in width, for example 2.8cm, 3.0cm or 3.8cm in width. The width of the margin of the handle which is adhered to the edge margin of the flexible sheet is then suitably 0.1 to 1.0cm, more suitably is 0.15 to 0.5cm and is preferably 0.2 to 0.3cm.

25 In order to avoid maceration of the underlying skin in this overlap area of the flexible sheet and handle the dressing in this area will favourably have a moisture vapour transmission rate of at least $300\text{g}^{-2} 24\text{h}^{-1}$ at 37°C and 100% to 10% relative humidity

5 difference, more favourably the rate will be at least 500gm⁻² 24h⁻¹ and preferably be at least 700gm⁻² 24h⁻¹.

In a further embodiment of this invention a further handle may be placed on the edge of the dressing opposite the handle with the dividing line and hole.

10 Suitable release sheets for covering exposed adhesive areas prior to use include silicone release coated papers and plastics coated papers and release coated films such as silicone coated polyethylene. A favoured release sheet is a silicone release/polyethylene coated paper known as Steralease No. 15 (Trade mark, available from Sterling Coated Paper Limited).

The adhesive layer of the dressing is protected by a first and second release sheet.

20 In a preferred form the second release sheet protects the adhesive layer on the handle and is folded back to form a second tab. The first release protects the adhesive layer on the flexible sheet of the dressing and a part of this first release sheet, which is not in contact with the adhesive layer, forms a first tab which covers part of the second tab. Preferably the second

5 tab is longer than the first tab. In a further preferred embodiment the second tab when folded back extends beyond the edge of the dressing.

10 Preferably the second release sheet which protects the adhesive layer on the handle has a hole and a dividing line in it matching exactly the hole and dividing line in the handle.

15 In a further preferred form of the dressing a portion is cut out of the second tab so that when it is folded back on the second release sheet the cut-out portion of the second tab will overlay that portion of the hole in the second release sheet covered by the second tab. Preferably the first tab has an aperture cut so that when it covers the second tab the edges of the aperture line up with the edges of the hole in the second release sheet and the handle.

20 The dressing of the invention will usually have a rectangular shape. Suitable dressings have a size of 5cm x 5cm to 20cm x 20cm for example 6cm x 8cm, 10cm x 10cm, 10cm x 15cm, 15cm x 15cm etc.

5 The dressing of the invention is preferably
sterile. The dressing of the invention is
advantageously provided within a bacteria proof pack
such as a sealed aluminium foil or paper/plastics film
pouch. Sterilization of the dressing can be carried out
10 by a conventional sterilizing method such as ethylene
oxide, electron or gamma radiation.

15 In another aspect the invention provides a process
of making a dressing of the invention which comprises
attaching the edge margin of a handle to an edge margin
of a flexible sheet and then the handle has a dividing
line cut inwardly from one side edge and a hole punched
in the handle area.

20 Suitable backing films, flexible sheets and handles
for use in the process of the invention are described
hereinbefore in relation to the dressing of the
invention.

25 The backing film may be formed by casting or
extrusion onto a support film, usually the non-release
surface of a conventional release paper or polymer. The
adhesive layer may be formed by casting or transfer
coating onto the surface of the flexible film. The
adhesive surface of the flexible film may then be

5 transferred onto the release surface of the second release sheet and then the first release sheet placed over the remaining adhesive surface so that the tab portion overlaps onto the second release sheet. The three layer laminate is then cut into a strip having the width of the required dressing. The dividing line and hole are then cut in the dressing.

10 The handle when present may be formed by transfer coating an adhesive layer on a release paper onto the material forming the handle. This may then be cut into a strip of the appropriate width and attached to the edge of the flexible sheet portion of the backing film. The second release sheet is applied to the adhesive surface of the handle and the first release sheet is applied to the adhesive surface of the flexible sheet. The dividing line and hole are then cut in the handle area and second release sheet.

15 In another aspect the present invention provides a method for retaining a cannula on the body employing a dressing comprising a backing film coated on one face with an adhesive layer and first and second release sheets covering the adhesive layer in which there is a hole and a dividing line through the dressing said dividing line extending from the hole to one edge of the

5 dressing and second release sheet which method comprises separating the dressing along the dividing line and placing the part of the dressing containing the hole around the cannula, removing the first release sheet and adhering the exposed part of the dressing over the
10 puncture site and then removing in turn the two halves of the second release sheet so that the remainder of the dressing secures the cannula on the skin.

15 A preferred embodiment of the present invention will now be described with reference to the accompanying drawings in which:-

Figure 1 shows a plan view of a dressing of the invention.

20 Figure 2 shows a cross-section through a dressing of the invention illustrating the layers which are present therein.

Figure 3 shows a dressing of the invention adhered to the skin and around a tap connector.

25 Figure 1 shows a view from above of a dressing of the present invention. The adhesive coated flexible sheet portion of the backing film (1) is adhered to the

5 skin over the injection site. An adhesive coated handle (2) is attached along one edge to the adhesive coated flexible sheet (1). The handle (2) has extending inwardly from one side edge a dividing line (3) and at the end of the dividing line (3) but within the
10 boundaries of the handle (2) is a hole (4). The exposed adhesive surfaces of the flexible sheet (1) and the handle (2) are covered by first and second release sheets respectively which are removed prior to use. The second release sheet (5) which covers the adhesive on the handle
15 (2) is in the form of a folded piece of silicone release paper which may carry a dividing line and hole similar to that of the handle (2) or may be perforated along the line of the dividing line (3) in the handle.

20 Figure 2 shows a cross-section through a dressing of the invention showing the different layers which make up the dressing. The adhesive coated flexible sheet (1) comprises two layers, first a backing film (6) which is formed from a moisture vapour permeable polymeric film comprising for example a linear polyether or polyester polyurethane, an elastomeric polyester or other
25 hydrophilic polymer film which has a moisture vapour transmission rate of over $1600 \text{ gm}^{-2} 24\text{h}^{-1}$ at 37°C and 100% to 10% relative humidity difference. Second an adhesive layer (7) which is formed from a skin

5 compatible adhesive such as a polyvinylethyl ether or polyacrylate ester copolymer adhesive. Suitably the adhesive is moisture vapour permeable whereby the dressing has a moisture vapour transmission rate of over 300gm⁻² 24h⁻¹. Prior to use the adhesive surface is
10 covered by a first release sheet (8) formed from a silicone coated release paper. The handle (2) is also formed from 2 layers (9,10). The first a backing layer (9) is more rigid than the backing film (1) but is also formed from a moisture vapour permeable material. Since
15 this material is adhered to unbroken skin, the backing layer (9) may be a plasticised polyvinyl chloride film, a non-woven fabric or a net. The second layer (10) is an adhesive layer similar to that on the flexible sheet (1). The handle (2) is adhered to the adhesive coated
20 flexible sheet (1) along one edge and the remaining exposed adhesive surface is covered by a silicone-coated second release sheet (11) suitably in the form of a folded piece. The first release sheet (8) overlaps part of the second release sheet (11) to ensure that no adhesive surfaces are left exposed. The first (12) and second (13) tabs on the first and second release sheets respectively allow the release sheets to be removed
25 easily.

5 Figure 3 shows a dressing of the invention in position at an injection site. The adhesive coated flexible sheet (1) is adhered over the injection site (14) and over the indwelling catheter (15). The hole (4) and the dividing line (3) in the handle (2) are adapted to fit round a connector (16) which in this
10 illustration carries a tap.

15 In use the second tab (13) and handle (2) are held in one hand and the first tab (12) is held in the other hand. The first tab (12) is then pulled and the first release sheet (8) is removed from the adhesive coated flexible sheet (1). The adhesive coated backing film (1) is then adhered over the injection site and the catheter or cannula. The second tab (13) is then
20 grasped and pulled and the second release sheet (11) is removed. The dividing line (3) in the dressing enables the dressing to be placed around the connector (16) so that the hole (4) in the dressing goes around the connector (16) and the two parts of the handle (2) can be adhered to the skin around the connector (14).

25 Alternatively the dressing may be used as follows, the perforated dividing line (3) is torn through and the two arms of the handle (2) and the hole (4) are arranged to lie on either side of the connector (16). The first

5 tab (12) is used to remove the release sheet (8) from the adhesive surface of the flexible sheet (1) and this portion of the dressing is adhered to the skin over the injection site (14) and the indwelling catheter (15).
10 The second tab (13) now in two parts is used to expose in turn the adhesive surfaces of the handle (2) surrounding the connector (16) which are then adhered to the skin around the connector. Alternatively each half of the second tab in turn can be used to expose the adhesive surfaces of the divided handle such that the
15 handle halves cross one on top of the other on the skin under the connector to form a better seal around the connector and to secure the connector more firmly.

CLAIMS

5. 1. A dressing for retaining a cannula comprising a backing film coated on one face with an adhesive layer and first and second release sheets covering the adhesive layer characterised in that there is a hole and a dividing line through the dressing and second release sheet said dividing line extending from the hole to one edge of the dressing and second release sheet whereby when the second release sheet is removed the hole in the dressing is adapted to be placed around a cannula.
10. 2. A dressing as claimed in claim 1 in which the dividing line is a line of perforations.
15. 3. A dressing as claimed in either of claims 1 or 2 in which the hole is oval in which the long axis is from 20 to 30mm and the short axis is from 5 to 15mm.
20. 4. A dressing as claimed in claim 1 in which part of said second release sheet is folded back to form a second tab and a part of said first release sheet which is not in contact with the adhesive layer forming a first tab which covers part of said second tab, and wherein the second tab extends beyond the first tab.

5 5. A dressing as claimed in claim 1 in which one portion of the dressing is an adhesive coated handle in which the hole and dividing line are located in the handle.

10 6. A dressing as claimed in claim 5 in which the handle is made from a different material to the backing film.

7. A dressing as claimed in claim 6 in which the handle is an integral net.

15 8. A dressing as claimed in any one of claims 1 to 7 in which the backing layer is a flexible polymeric film of polyurethane of thickness from 15 to 50 μ m.

20 9. A dressing as claimed in any one of claims 1 to 8 in which the adhesive layer is formed from an acrylate ester copolymer adhesive and which has a weight per unit area of 10 to 75 gm^{-2} .

10. A dressing as claimed in any one of claims 1 to 9 in which the dressing has a moisture vapour transmission rate of at least 300 $gm^{-2} 24h^{-2}$ at 37°C and 100% to 10% relative humidity difference.

5 11. A dressing as claimed in any one of claims 1 to 10
in which the adhesive layer contains antibacterial
agent.

10 12. A dressing as claimed in claim 11 in which the
adhesive layer contains 5% by weight of the adhesive
chlorhexidine diacetate.

13. A dressing as claimed in any one of claims 1 to 12
in which the dressing is sterile and is provided in a
bacteria proof pack.